

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	MDL No. 02419
LITIGATION)	Docket No. 1:13-md-2419-RWZ
_____)	

This document relates to:

Handy v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14019-RWZ

Armetta v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14022-RWZ

Torbeck v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14023-RWZ

Kashi v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14026-RWZ

Bowman v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14028-RWZ

Dreich v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14029-RWZ

Davis v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14033-RWZ

Farthing v. Box Hill Surgery Center, LLC, et al.
No. 1:14-cv-14036-RWZ

**BOX HILL DEFENDANTS’ CONSOLIDATED MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT
CONCERNING PLAINTIFFS’ NEGLIGENCE CLAIMS DUE TO SUPERSEDING,
INTERVENING CAUSE**

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively “Defendants,” “Box Hill Defendants,” or “Box Hill”), by undersigned counsel, submit this memorandum of law in support of their Motion For

Summary Judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure and the authority cited below.

I. INTRODUCTION

In each of the above captioned cases, Plaintiffs asserted claims that the allegedly negligent acts of the Box Hill Defendants were the cause of Plaintiffs' injuries. The Box Hill Defendants now move for summary judgment on each of Plaintiffs' claims related to negligence because the undisputed facts demonstrate that both the negligence of NECC and the criminal actions of Mr. Barry Cadden constitute superseding, intervening causes that preclude the Box Hill Defendants from being held liable for Plaintiffs' injuries.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which otherwise do not apply to the singular claim addressed in this motion for summary judgment.

This action is among hundreds, if not thousands, of lawsuits across the United States arising out of the administration of a steroid—preservative free methylprednisolone acetate (hereinafter “MPA”)—manufactured, contaminated, and distributed by New England Compounding Pharmacy, Inc. a/k/a New England Compounding Center (hereinafter “NECC”), a now dissolved corporation in Massachusetts. NECC provided MPA for purchase nationally to many physicians, ambulatory surgery centers, clinics, and hospitals, including Defendant Box Hill Surgery Center, which is an ambulatory surgery center solely owned by Defendant Bhambhani. It is alleged that as a result of negligent manufacturing, cleaning and sterilization practices by NECC, as well as improper testing and “clean-room” design, that certain vials or batches of MPA became contaminated with fungus in 2012 and may have caused varying levels of harm or injury to patients, who had received the MPA from their health care providers. It is alleged that the

contaminated vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102012@51 (BUD 2/6/2013).

The Box Hill Defendants ordered preservative-free MPA from NECC on August 13, 2012, prior to the recall. NECC fulfilled the Box Hill Defendants' order with vials from Lot # 06292012@26, which was one of the lots eventually recalled. Of significance, NECC fulfilled the Box Hill Defendants' order with vials from Lot # 06292012@26 prior to receiving any results from the sterility testing. Dreisch Complaint at 19, ¶ 64. In addition to fulfilling orders prior to receiving results from the sterility testing, Plaintiffs' experts have testified that NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumers and potential consumers. *See* Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 10**. He further testified that actions taken by NECC *after* the Box Hill Defendants ordered preservative-free MPA were against the law. *Id.*

The MPA in the recalled lots was shipped to health care providers, including the Box Hill Defendants, who administered the drugs to patients before it was discovered that the lots were contaminated. These lots were recalled by NECC under pressure from the CDC on or about September 26, 2012, but not until after numerous patients fell ill, and some died, after developing fungal meningitis or other neurologic or infectious process.

As a result of the outbreak, the owners, pharmacists, and many of the employees of NECC were indicted on criminal counts of fraud and other transgressions in this very Court, including acts that contributed to the contamination of the MPA, through no fault of the Box Hill Defendants or the other health care providers who administered the contaminated MPA unknowingly. In fact, on March 22, 2017, a jury found Mr. Cadden guilty of racketeering, racketeering conspiracy, mail

fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.¹ He was sentenced to nine years in prison.²

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment as to Plaintiffs' negligence claims because the intervening negligent acts of both NECC and Barry Cadden constitute superseding causes that preclude the Box Hill Defendants from any liability as an original tortfeasor.

II. STATEMENT OF FACTS³

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").⁴

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).⁵

3. The Plaintiffs' claims against the Box Hill Defendants arise from alleged injuries suffered from potential exposure to MPA administered by Dr. Bhambhani and the Box Hill Defendants while performing epidural steroid injection procedures.⁶

¹ *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>. As that criminal trial and the verdict occurred in this Court, this Court can take judicial notice of the result.

² *Id.*

³ The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.

⁴ Dreisch Complaint at 3, ¶ 1.

⁵ Dreisch Complaint at 17, ¶ 51.

⁶ Dreisch Complaint at 37, ¶ 145.

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.⁷

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center (“NECC”) even in just the five months preceding the meningitis outbreak at issue.⁸

6. NECC was regulated and inspected by the U.S. Food and Drug Administration (“FDA”).⁹ In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that “the Federal Food, Drug, and Cosmetic Act (“FDCA”) establishe[d] agency jurisdiction over ‘new drugs,’ including compounded drugs.”¹⁰

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Womens Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.¹¹

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to “follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure,” failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that

⁷ See Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.

⁸ See NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.

⁹ See FDA Warning Letter, attached as **Exhibit 3**.

¹⁰ *Id.*

¹¹ See Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women’s Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women’s Vendor Audit Survey Form, attached as **Exhibit 6**.

recorded bacteria and mold in the clean rooms used to produce “sterile” drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.¹²

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.¹³

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.¹⁴ As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.¹⁵

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.¹⁶

12. NECC’s actions fell below the standard of care with regard to the contaminated lots of MPA.¹⁷

13. The Box Hill Defendants’ procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were

¹² Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64.

¹³ See Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; see also Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

¹⁴ *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

¹⁵ Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

¹⁶ See Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

¹⁷ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

contaminated.¹⁸ Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.¹⁹

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.²⁰

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.²¹

III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is "entitled to judgment as a matter of law" when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id.* at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id.* at 324. To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth "specific facts showing there is a genuine issue for trial." *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

¹⁸ See Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.

¹⁹ See *id.*

²⁰ See *id.*, 64:7–65:1, excerpts attached as **Exhibit 7**.

²¹ See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

IV. LEGAL ARGUMENT

One of Plaintiffs' primary contentions in the above related matters is that the Box Hill Defendants were negligent and that the alleged negligence caused Plaintiffs' injuries. However, the Box Hill Defendants, even if presumed to be negligent for purposes of this Motion, are precluded from liability with regard to Plaintiffs' negligence claims because the actions of both NECC and Barry Cadden constitute superseding, intervening causes. Stated differently, even if Plaintiffs' injuries might not have occurred "but for" an antecedent act of the Box Hill Defendants, liability may not be imposed because the intervening negligent acts of NECC and Barry Cadden were the moving and effective cause of Plaintiffs' injuries. *See Peterson v. Underwood*, 258 Md. 9, 16 (1970). Superseding causation is dispositive as to Plaintiffs' negligence claims because superseding acts of negligence relieve the original tortfeasor from liability for Plaintiffs' alleged injuries. Accordingly, Plaintiffs' claims fail as a matter of law and the Box Hill Defendants are entitled to summary judgment.

The elements of negligence are well-established in Maryland. "First, the defendant must be under a duty to protect the plaintiff from injury. Second, the defendant must fail to discharge that duty. Third, the plaintiff must suffer actual loss or injury proximately resulting from that failure." *Lamb v. Hopkins*, 303 Md. 236, 241 (1985). Thus, in order to be found liable for Plaintiffs' alleged damages, any negligent act by the Box Hill Defendants' alleged negligence must have been the proximate cause of the harms. *See Stone v. Chicago Title Ins. Co. of Md.*, 330 Md. 329, 337 (1993).²² Proximate cause is a question of law in cases, such as this matter, where reasoning minds cannot differ. *Pittway Corp. v. Collins*, 409 Md. 218, 253 (2009).

²² Maryland's highest court has provide a specific framework for courts to utilize when analyzing proximate cause. "Proximate cause ultimately involves a conclusion that someone will be held legally responsible for the consequences of an act or omission. This determination is subject to considerations of fairness or social policy as well as mere causation." *Peterson v. Underwood*, 258 Md. 9, 16 (1970).

A defendant's negligence is not deemed to be the proximate cause of an injury when the natural and ordinary sequence following the original act is actually broken by a responsible intervening cause. *Hartford Ins. Co. v. Manor Inn of Bethesda, Inc.*, 335 Md. 135, 160 (1994). An original tortfeasor's liability is terminated when the chain of causation is broken when an intervening force amounts to a superseding cause. *Yonce v. SmithKline Beecham Clinical Laboratories, Inc.*, 111 Md. App. 124, 140 (1996). A finding that an intervening act of a third party amount to a superseding cause is significant because it prevents the original tortfeasor from being held liable for injuries sustained by a plaintiff. *See* RESTATEMENT (SECOND) OF TORTS § 440.

Section 442 of the Restatement (Second) of Torts, which “establishes the test that has been applied in Maryland courts for determining when an intervening negligent act arises to the level of a superseding cause,” enumerating factors to be considered when determining whether an intervening cause amounts to a superseding cause:

The following considerations are of importance in determining whether an intervening force is a superseding cause of harm to another:

- (a) the fact that its intervention brings about harm different in kind from that which would otherwise have resulted from the actor's negligence;
- (b) the fact that its operation or the consequences thereof appear after the event to be extraordinary rather than normal in view of the circumstances existing at the time of its operation;
- (c) the fact that the intervening force is operating independently of any situation created by the actor's negligence, or, on the other hand, is or is not a normal result of such a situation;
- (d) the fact that the operation of the intervening force is due to a third person's act or his failure to act;
- (e) the fact that the intervening force is due to an act of a third person which is wrongful toward the other and subjects the third person to liability to him;
- (f) the degree of culpability of a wrongful act of a third person which sets the intervening force in motion.

Pittway, 409 Md. at 248; Section 442 of the RESTATEMENT (SECOND) OF TORTS.

The negligent acts of NECC, as well as the criminal acts of Barry Cadden, amount to superseding, intervening causes that relieve the Box Hill Defendants from any liability resulting from Plaintiffs' alleged injuries.

A. NECC's negligent actions amount to superseding, intervening causes of Plaintiffs' injuries that relieve the Box Hill Defendants from liability.

Plaintiffs in the above related actions have asserted a negligence claim against the Box Hill Defendants and, in support of which, provided an extensive list of duties that were allegedly breached. Plaintiffs further contend that the breach of such duties was the proximate cause of the alleged injuries. It is undisputed, however, that various settling defendants and non-parties were negligent. Plaintiffs' claims against the Box Hill Defendants as to negligence fail as a matter of law because the negligent acts and omissions of the other defendants constitute superseding, intervening causes that preclude the Box Hill Defendants from liability.

It is undisputed that the actions of NECC and other defendants, as well as non-parties, constituted intervening negligent causes of Plaintiffs' injuries. In fact, Plaintiffs, by their very own admissions and through their own experts, have established that the negligence of NECC caused the asserted injuries. Dr. Chason, Plaintiffs' expert pharmacist, testified in his deposition that NECC's actions fell below the standard of care with regard to the contaminated lots of MPA, and that NECC's conduct caused the injuries to the patients in these cases. *See* Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 11**. Dr. Saberski, Plaintiffs' expert in internal medicine, anesthesiology, and pain management, also testified that NECC, and not the Box Hill Defendants, caused the contamination of the MPA. *See* Deposition Transcript of Dr. Lloyd R. Saberski, 64:7–65:1, excerpts attached as **Exhibit 10**. Dr. Saberski further testified

that NECC failed in the summer and fall of 2012 to fulfill its duty to accurately represent the safety and quality of its products to consumers and potential consumers and that, in his opinion, NECC broke the law. *See id.*, 65:5–65:18, excerpts attached as **Exhibit 10**.

In light of the Plaintiffs having established that the actions of NECC, as well as other defendants and non-parties, constituted intervening causes of the Plaintiffs' injuries, the Court must now determine whether such intervening causes amounted to superseding causes. A superseding cause arises primarily when "unusual" and "extraordinary" independent intervening negligent acts occur that could not have been anticipated by the original tortfeasor. *Pittway Corp.*, 409 Md. at 249 (quoting *McGowans v. Howard*, 234 Md. 134, 138 (1964)). Maryland courts consider *both* the foreseeability of the harm suffered by the plaintiffs as well as the foreseeability of the intervening acts in determining superseding causation. *Pittway Corp.*, 409 Md. at 252–53 (emphasis in original) (citations omitted). Injuries that result from a highly extraordinary event will not be deemed foreseeable and, in such a case, the court may declare the intervening cause to be a superseding cause of the plaintiff's injury. *Pittway*, 409 Md. at 247; RESTATEMENT (SECOND) OF TORTS § 435(2) cmt. c (1965).

NECC's intervening negligent acts will be deemed to be superseding causes of Plaintiffs' alleged harms, therefore precluding the Box Hill Defendants from liability, if NECC's actions were not foreseeable. In the instant matter, the Box Hill Defendants ordered and used NECC products, specifically including preservative-free MPA, with no contamination issues or adverse events for years prior to the outbreak. *See* Deposition Transcript of Ritu T. Bhambhani, M.D., 97:12–98:15, excerpts attached as **Exhibit 12**. In addition to the good results that the Box Hill Defendants had with the NECC products, Dr. Bhambhani also noted in her deposition that she was unaware of any regulatory issues with NECC's products or operations. *See id.*, 106:04–109:04,

excerpts attached as **Exhibit 12**. Further eliminating the chances that the Box Hill Defendant could have anticipated NECC's negligent intervening actions is the fact that much of NECC's negligent actions occurred *after* the Box Hill Defendant purchased the contaminated MPA. Plaintiffs state in their Complaint that, upon receiving orders, NECC "did not follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure," NECC failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce "sterile" drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing. Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64. Ultimately, Plaintiffs' injuries were caused by what has been widely considered to be the largest public health crisis ever caused by a pharmaceutical product.²³ NECC's negligent and criminal conduct unquestionable fits the mold as being highly "extraordinary" and "unusual" and, based on the undisputed facts, no reasonable jury could find that either Plaintiffs' injuries or NECC's actions were foreseeable. Accordingly, the uncontroverted facts in this matter seamlessly align with the factors that control this Court's analysis in reaching the conclusion that NECC's actions constitute a superseding, intervening cause.

The Box Hill Defendants are entitled to summary judgment on this matter because they are precluded as a matter of law from being held liable for Plaintiffs' alleged injuries.

B. Barry Cadden's criminal amounts to superseding, intervening causes of Plaintiffs' injuries that relieve the Box Hill Defendants from liability.

Under Maryland law, the criminal act of a third party can constitute a superseding, intervening cause that precludes liability of the initial actor. *See Troxel v. Iguana Cantina, LLC*,

²³ *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (MAR. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

201 Md. App. 476, 509–10 (2011) (citing RESTATEMENT (SECOND) OF TORTS § 448). In determining whether criminal acts by a third party can preclude liability of the initial actor when the injury was caused by criminal acts, Maryland courts have adopted Section 448 of the RESTATEMENT (SECOND) OF TORTS:

The act of a third person in committing an intentional tort or crime is a superseding cause of harm to another resulting therefrom, although the actor's negligent conduct created a situation which afforded an opportunity to the third person to commit such a tort or crime, unless the actor at the time of his negligent conduct realized or should have realized the likelihood that such a situation might be created, and that third person might avail himself of the opportunity to commit such a tort or crime.

Troxel v. Iguana Cantina, LLC, 201 Md. App. 476, 509–10 (2011); *Scott v. Watson*, 278 Md. 160 (1976); *Hemmings v. Pelham Wood Ltd. Liab. Ltd. P'ship*, 275 Md. 522 (2003).

It is undisputed in the instant matter that Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury on March 22, 2017 of racketeering and mail fraud in connection with the 2012 nationwide fungal meningitis outbreak.²⁴ Specifically, Mr. Cadden directed and authorized the shipping of contaminated MPA to NECC customers nationwide.²⁵ Additionally, he authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients.²⁶ Mr. Cadden also repeatedly took steps to shield NECC's operations from regulatory oversight by the FDA, claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions and routinely used fictional and celebrity names on fake prescriptions in order to dispense drugs.²⁷ The 2012 outbreak is considered to be the largest public health crisis

²⁴ *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

ever caused by a pharmaceutical product.²⁸ Following a nine-week trial, Mr. Cadden was convicted of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.²⁹ As a result of his criminal conduct, Mr. Cadden has been sentenced to nine years in prison for these charges.³⁰

Mr. Cadden's criminal activity gave rise to the circumstances that ultimately caused the harm alleged to be suffered by Plaintiffs and, as such, the Box Hill Defendants cannot be held liable to the Plaintiffs unless Mr. Cadden's criminal acts were foreseeable. Pursuant to Maryland law, the Box Hill Defendants can only be found liable if, at the time they ordered medications from NECC, they realized, or should have realized, both that they had somehow created a situation in which Mr. Cadden would commit such criminal acts *and* that Mr. Cadden was likely to avail himself of such an opportunity. Stated differently, the Box Hill Defendants cannot be held liable to Plaintiffs unless a jury is able to find that the Box Hill Defendants knew, or should have known, that ordering medications from NECC availed Mr. Cadden of the opportunity to commit the criminal acts for which he was found guilty and that Mr. Cadden would likely seize the opportunity to so act. The facts in this matter, even when viewed in a light most favorable to Plaintiffs, fall drastically short of even remotely supporting such a conclusion.

As a preliminary matter, the Box Hill Defendants had been ordering and using NECC products, specifically including preservative-free MPA, without adverse results for years prior to the outbreak. *See* Deposition Transcript of Ritu T. Bhambhani, M.D., 97:12–98:15, excerpts attached as **Exhibit 12**. In addition to the good results that the Box Hill Defendants had with the

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison*, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

NECC products, Dr. Bhambhani also noted in her deposition that she was unaware of any regulatory issues with NECC's products or operations. *See id.*, 106:04–109:04, excerpts attached as **Exhibit 12**. In short, there is nothing in the record to indicate that the Box Hill Defendants knew, or had reason to know that Mr. Cadden would commit a criminal act.

Further eliminating any likelihood that the Box Hill Defendants may have been aware or should have been aware of any potential criminal acts by Barry Cadden and/or NECC is the fact that NECC was approved by every regulatory agency exercising oversight over its products and operations. Specifically, they were subject to oversight from the FDA as well as the Massachusetts Board of Pharmacy, and were approved by the Maryland Board of Pharmacy. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, and Brigham and Women's Hospital, a highly accredited and respected healthcare institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012. *See* Brigham and Women's Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 13**; Brigham and Women's Vendor Audit Survey Form, attached as **Exhibit 14**.

The uncontroverted facts in this matter permit but one conclusion and, as such, the question of whether the criminal acts of Mr. Cadden constitute a superseding, intervening cause becomes one of law. *See Pittway Corp. v. Collins*, 409 Md. at 253. Accordingly, the Box Hill Defendants are entitled to judgment as a matter of law because liability is precluded as a result of Mr. Cadden's criminal acts.

V. CONCLUSION

For the foregoing reasons, the Box Hill Defendants respectfully request that the Court grant its motion for summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of September 2017, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby
Gregory K. Kirby, Esq.